SM

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,586	05/08/2001	Glenn L. Millhauser	407T-980910US	2641

22798 7590 04/30/2004

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,586	MILLHAUSER ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/7/03, 1/23/04, 2/3/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *1-69 and 71-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/29/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group IV (claims 39-44, 66-67, and 70) and specie A (a specific polypeptide corresponding to MARP-33 (SEQ ID NO: 3)), filed 4/7/03, as well as amendments and drawings, filed 1/23/03, and 2/3/04, are acknowledged. Claims 1-38, 45-65, 68, and 71-86 are withdrawn from consideration as being drawn to non-elected Groups. Applicants incorrectly state that claims 39, 66, and 70 are generic and claims 39-44, 66-67, and 70 are readable on the elected species. In fact, only claim 70 is readable on the elected specie. Therefore, claims 39-44, 66, and 67 are withdrawn from consideration as being drawn to a non-elected specie (a specie other than a polypeptide corresponding to MARP-33 (SEQ ID NO: 3)).

Applicants' traversal is on the grounds that the restriction between Groups I and IV is unnecessary. Applicants' state that according to MPEP § 803, the Examiner should examine all claims in an application, even though they are directed to distinct inventions, unless there is a serious burden. Applicants state a search of art relevant to the peptides is expected to identify, if it exists, relevant to the use of the peptides such that there is no extra search burden.

The applicants' request to combine Groups I and IV into one invention was found unpersuasive because of the following reasons (summarized from the restriction paper):

Inventions in Groups I and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the peptide of Group IV may be utilized in distinct usages as needed in Group I in a method of modulating activity of a melanocortin receptor, or alternatively, in cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together. A search of polypeptides does not necessarily entail a search of methods of using such polypeptides and each invention type clearly has non-overlapping subject matter with the other invention types. Because distinctness and divergent subject matter appear to be present regarding Groups I and IV, the restriction is considered to be appropriate.

The requirements are still deemed proper and are therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to methods and compounds for modulating melanocortin receptor ligand binding and activity, whereas in contrast the elected claims are specifically directed to a pharmaceutical composition.

The drawings, filed 1/23/04, are approved by the Examiner.

Claim 70 is herein under examination.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 70 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 27 of copending Application No. 10/111727. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

PATENTABLE UTILITY GUIDELINES

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 70 is rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The critical limitation of claim 70 is the polypeptide sequence, SEQ ID NO: 3 (MARP-33). The specification states MARP-33 provides both activity and receptor specificity against melanocortin receptors 3 and 4 (MC3r and MC4r) (page 4, first paragraph). The specification also states a method of treating a disease state in mammals that is alleviated by a treatment with SEQ ID NO: 3 such as a wasting syndrome which represents a specific utility. Other statements in the specification regarding using MARPs for identifying peptides, peptidomimetics, or small molecules that modulate melanocortin receptor activity (page 37, second and third paragraphs), binding assays (page 37), and pharmaceutical preparations (page 42) are generic, rather than specific, utilities.

The specific utility of treating a wasting syndrome appears to be an assertion without factual support. It appears that further research would be needed to confirm this "real world" context of use. Applicants provide examples involving the synthesis, NMR experiments, and structural calculations of SEQ ID NO: 2 and N-alpha-acetyl-MARP(Arg25Ala) (pages 49-92); screening examples for SEQ ID NO: 5 (page 93); and synthesis and binding assays for

peptidomimetics (pages 94-95). However, they do not provide data to confirm that the MARPs, particularly SEQ ID NO: 3, play a role in treating a wasting syndrome. Further research may prove that the sequence of SEQ ID NO: 3 can play a crucial role in alleviating this syndrome, or alternatively, that its presence/role is inconsequential. Identifying a sequence itself does not define a "real world" context of use.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Due to a lack of either an art recognized or alleged well established utility, the instant invention has been rejected due to also lacking the required combination of a specific, substantial, and credible utility. Although it may be credible that the MARP of SEQ ID NO: 3 in a pharmaceutical composition may treat a wasting syndrome, the lack of a substantial utility, as explained above, sufficiently supports this rejection.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The

factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claim 70 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

Due to the large quantity of experimentation necessary to determine activity or property of the disclosed polypeptide, such that it can be determined how to use the claimed sequence, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, and the breadth of the claim which fails to recite a particular biological activity, the specification fails to teach the skilled artisan how to use the claimed invention.

Without further data or sound scientific reasoning, it appears speculative whether the polypeptide of SEQ ID NO: 3 plays a role in any of the asserted utilities as discussed above in the 35 U.S.C. § 101 rejection. With this in mind, additional evidence is necessary in order to satisfy the current lack of enablement. Several options exist to overcome this lack of enablement

issue, such as supplying additional data or other scientific reasoning that would lead one of ordinary skill in the art to be able to make and/or use the present invention.

Also, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to the 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

April 19, 2004

ARDIN H. MARSCHEL
PRIMARY EXAMINER 4/29/04